

### **Listing of Claims:**

Claims 1-14 (cancelled)

Claim 15 (previously presented): The process of claim 34 further comprising drying the coated charged nucleus.

Claim 16 (currently amended): The process of claim 34, wherein said binder in said aqueous or hydroalcoholic solution-suspension is selected from the group consisting of saccharose, starch, methylcellulose, ~~CMC, HPC, HPMC~~ carboxymethyl cellulose (CMC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl cellulose (HPMC), polyvinyl pyrrolidone (PVP), dextrin or gum arabic, either alone or mixed, dissolved in water, ethanol or a mixture of both at 50% (v/v).

Claim 17 (cancelled)

Claim 18 (previously presented): The process of claim 34, wherein said surface-active agent present in said aqueous or hydroalcoholic solution-suspension is selected from the group consisting of sodium lauryl sulphate, polysorbate, poloxamer or other ionic and non-ionic surface-active agents.

Claim 19 (previously presented): The process of claim 34, wherein said filling material in said aqueous or hydroalcoholic solution-suspension is selected from the group consisting of lactose, starch, saccharose and microcrystalline cellulose.

Claim 20 (currently amended): The process of claim 34, wherein said disintegrating-swelling excipient in said aqueous or hydroalcoholic solution-suspension is selected from the group consisting of starch, ~~CMC~~ calcium carboxymethyl cellulose (CMCCa), sodium glycolate starch and ~~L-HPC~~ hydroxypropyl cellulose (L-HPC).

Claim 21 (currently amended): The process of claim 34, wherein said enteric coating polymer in said external gastro-resistant coating is selected from the group consisting of methyl cellulose, ~~HEC, HBC, HPMC~~ hydroxyethyl cellulose (HEC), hydroxybutyl cellulose (HBC), hydroxypropylmethyl cellulose (HPMC), ethyl cellulose, ~~HMC, HPC~~ hydroxymethyl cellulose (HMC), hydroxypropyl cellulose (HPC),

polyoxyethylene glycol, castor oil, cellulose phthalic acetate, phthalate of HPMC, succinate acetate of HMC, sodium carboxymethylamylopectin, chitosan, alginic acid, carrageenans, galactomannons, tragacanth, shellac, agar-agar, gum arabic, guar gum, xanthan gum, polyacrylic acids, methacrylics and their salts, PVA polyvinyl alcohol (PVA), polyethylene and polypropylene oxides and mixtures thereof.

Claim 22 (currently amended): The process of claim 34 41, wherein said plasticizer in said external gastro-resistant coating is selected from the group consisting of ~~TEC~~, ~~PEG~~ triethyl citrate (TEC), polyethylene glycol (PEG), cetyl alcohol and stearyl alcohol.

Claim 23 (previously presented): The process of claim 34, wherein said surface-active agent in said aqueous or hydroalcoholic solution-suspension is selected from the group consisting of sodium lauryl sulphate, polysorbate and poloxamer.

Claim 24 (currently amended): The process of claim 34 41, wherein said pigment in said external gastro-resistant coating layer is selected from the group consisting of titanium dioxide and iron sesquioxide.

Claim 25 (currently amended): The process of claim 34 41, wherein said lubricant in said external gastro-resistant coating layer is selected from the group consisting of talc, magnesium stearate and glyceryl mOhnostearate.

Claims 26-29 (cancelled)

Claim 30 (previously presented): The process of claim 34 wherein the filling material is selected from the group consisting of mannitol, sorbitol or gelatin.

Claim 31 (currently amended): The process of claim 34 wherein the alkaline reacting compound is selected from the group consisting of sodium, potassium, aluminum or calcium acetate; sodium, potassium, aluminum or calcium glycerophosphate; (tris)-hydroxymethylaminemethane (tromethamine); N-methylglucamine, 2-amine-2-methyl-1, 3-propanediol; 2-amine-2-methyl-1propanole; sodium, potassium, magnesium, calcium, aluminum or aluminum hydroxide salts of ~~aminoacids like lysine, glutamic acid, glycine or pyrimidinecarboxylic acids, like nicotinic acid,~~ amino acids, salts derived from organic or weak

inorganic acids, and bases like ~~guanidine~~ and basic ~~aminoacids like arginine, histidine, lysine and tryptophane~~ amino acids.

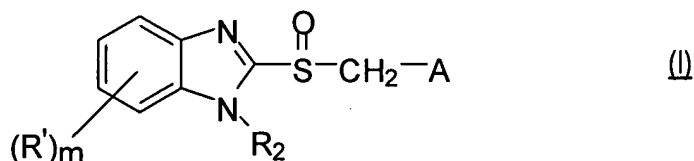
Claim 32 (cancelled)

Claim 33 (currently amended): The process of claim 34 ~~41~~ wherein the plasticizer is selected from the group consisting of diethyl phthalate, dibutyl phthalate, dimethyl phthalate, dioctyl adipate, dioctyl phthalate, dioctyl terephthalate, butyloctyl phthalate, triethylene glycol di-2-ethylhexanoate, trioctylmethyleate, glyceryl triacetate, glyceryl tripropionate and, 2,2,4-trimethyl-1, 3-pentanedioldiisobutyrate.

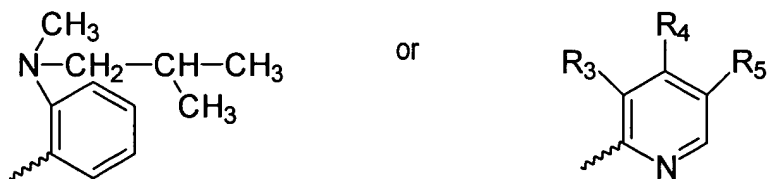
Claim 34 (currently amended): A process for making an oral pharmaceutical preparation comprising:

a) coating an inert nucleus to form a substantially non-porous layer thereon by spraying on the nucleus an aqueous or hydroalcoholic suspension-solution, which comprises:

- an active ingredient of anti-ulcer activity of general formula I:



wherein A is:



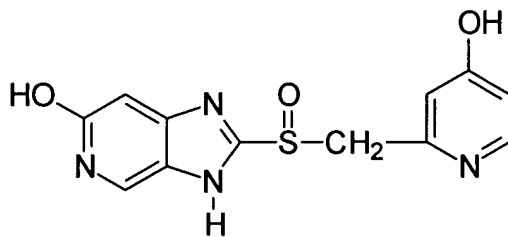
wherein R<sup>3</sup> and R<sup>5</sup> are the same or different, and may be hydrogen, alkyl, alkoxy, or alkoxyalkoxy;  
R<sup>4</sup> is hydrogen, alkyl, alkoxy which can be ~~fluorated~~ fluorinated, alkoxyalkoxy, or optionally alkoxycycloalkyl;

R<sup>1</sup> is hydrogen, alkyl, halogen, cyano, carboxy, carboalkoxy, carboalkoxyalkyl, carbamoyl,

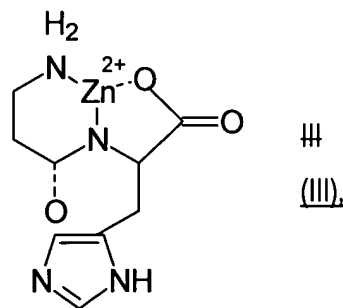
carbamoylalkyl, hydroxy, alkoxy, hydroxyalkyl, trifluoromethyl, acyl, carbamoyloxy, nitro, acyloxy, aryl, aryloxy, alkylthio or alkylsulfinyl;

R<sup>2</sup> is hydrogen, alkyl, acyl, carboalkoxy, carbamoyl, alkylcarbamoyl, dialkylcarbamoyl, alkylcarbonylmethyl, alkoxycarbonylmethyl or alkylsulfonyl; and, m is a whole number from 0 to 4;

or of general formula II or III,



II (II)



III (III)

an alkaline reacting compound, and

- at least one pharmaceutically acceptable excipient selected from the group ~~which includes~~ consisting of: a binder, ~~an alkaline reaction compound~~, a surface-active agents agent, a filling material and a disintegrating-swelling excipients excipient;

b) drying the active layer formed during said spraying to form a charged nucleus; and

c) coating the charged nucleus by spraying a solution which contains an enteric coating polymer with at least one pharmaceutically acceptable excipient ~~selected from the group comprising: a plasticizer, a surface active agent, a pigment and a lubricant~~, to form a gastro-resistant external coating layer on said charged nucleus;

wherein the steps a) to c) are performed in a Wurster-type fluidized bed coater.

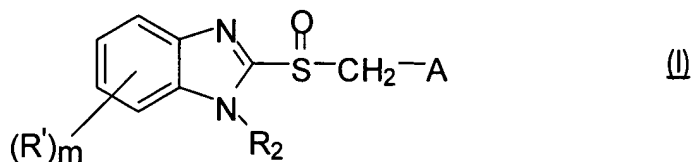
Claim 35 (cancelled)

Claim 36 (currently amended): A process for making an oral pharmaceutical preparation comprising:

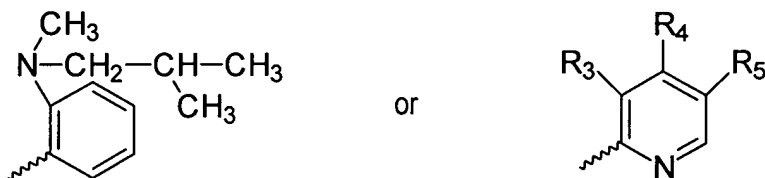
a) coating an inert nucleus in a fluidized bed coater to form a substantially non-porous

layer thereon by spraying on the nucleus an aqueous or hydroalcoholic suspension-solution, which comprises:

- an active ingredient of anti-ulcer activity of general formula I:



wherein A is



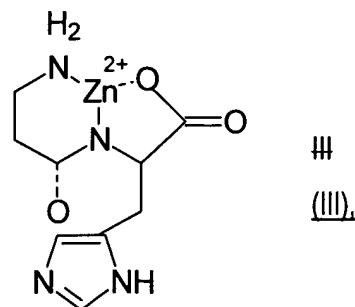
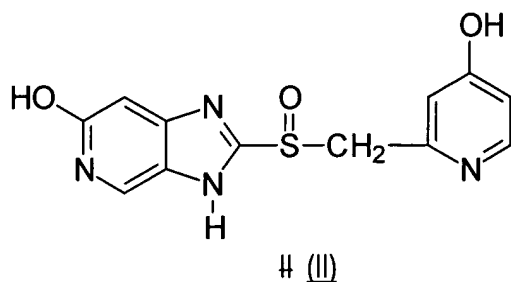
wherein R<sup>3</sup> and R<sup>5</sup> are the same or different, and may be hydrogen, alkyl, alkoxy, or alkoxyalkoxy;

R<sup>4</sup> is hydrogen, alkyl, alkoxy which can be ~~fluorated~~ fluorinated, alkoxyalkoxy, or optionally alkoxycycloalkyl;

R<sup>1</sup> is hydrogen, alkyl, halogen, cyano, carboxy, carboalkoxy, carboalkoxyalkyl, carbamoyl, carbamoylalkyl, hydroxy, alkoxy, hydroxyalkyl, trifluoromethyl, acyl, carbamoyloxy, nitro, acyloxy, aryl, aryloxy, alkylthio or alkylsulfinyl;

R<sup>2</sup> is hydrogen, alkyl, acyl, carboalkoxy, carbamoyl, alkylcarbamoyl, dialkylcarbamoyl, alkylcarbonylmethyl, alkoxycarbonylmethyl or alkylsulfonyl; and, m is a whole number from 0 a to 4;

or of general formula II or III,



an alkaline reacting compound, and

- at least one pharmaceutically acceptable excipient selected from the group ~~which includes~~ consisting of: a binder, ~~an alkaline reaction compound,~~ a surface-active agents agent, a filling material and a disintegrating-swelling excipients excipient;

b) drying the active layer formed during said spraying to form a charged nucleus in said fluid bed coater; and

c) coating the charged nucleus in the fluid bed coater by spraying on said charged nucleus a solution which contains an enteric coating polymer with at least one pharmaceutically acceptable excipient ~~selected from the group comprising: a plasticizer, a surface active agent, a pigment and a lubricant,~~ to form an gastro-resistant external coating layer thereon.

wherein the fluidized bed coater is a Wurster-type fluidized bed coater.

Claims 37 to 38 (cancelled)

Claim 39 (previously presented): The process of claim 34 wherein the oral pharmaceutical preparation is stable.

Claim 40 (previously presented): The process of claim 36 wherein the oral pharmaceutical preparation is stable.

Claim 41 (new): The process of claim 34 wherein the least one pharmaceutically acceptable excipient is at least one of a plasticizer, a surface-active agent, a pigment and a lubricant.

Claim 42 (new): The process of claim 34 wherein the inert nucleus has an initial size between 200 and 1800 micrometers.

Claim 43 (new): The process of claim 42 wherein the inert nucleus has an initial size of 600 to 900 micrometers.

Claim 44 (new): The process of claim 34 wherein the inert nucleus is a neutral spherical microgranule which includes in its composition at least two of: sorbitol, mannitol, saccharose, starch, microcrystalline cellulose, lactose, glucose, trehalose, maltitol or fructose.

Claim 45 (new) The process of claim 36 wherein the least one pharmaceutically acceptable excipient is at least one of a plasticizer, a surface-active agent, a pigment and a lubricant.

Claim 46 (new): The process of claim 34, wherein said alkaline reacting compound in said aqueous or hydroalcoholic solution-suspension is selected from the group consisting of trisodium phosphate, disodium phosphate, magnesium oxide, magnesium hydroxide, magnesium carbonate, aluminium hydroxide, carbonate, phosphate or citrate of aluminium, calcium, sodium or potassium, and the mixed compounds of aluminium/magnesium  $\text{Al}_2\text{O}_3 \cdot 6\text{MgO} \cdot \text{CO}_2 \cdot 12\text{H}_2\text{O}$  or  $\text{MgO} \cdot \text{Al}_2\text{O}_3 \cdot 2\text{SiO}_2 \cdot n\text{H}_2\text{O}$  and alkaline reacting amino acids.

Claim 47 (new): The process of claim 31 wherein the hydroxide salts are of amino acids such as lysine, glutamic acid, glycine or pyrimidinecarboxylic acids such as nicotinic acid.

Claim 48 (new): The process of claim 31 wherein the basic amino acids are arginine, histidine, lysine and triptophane.

Claim 49 (new): The process of claim 34 wherein the enteric coating polymer present in the external gastro-resistant coating is selected from the group consisting of phthalate of hydroxypropylmethyl cellulose, succinate acetate of hydroxymethyl cellulose, polyvinyl acetate phthalate, and cellulose acetate trimethylate.

Claim 50 (new): The process of claim 34 wherein the alkaline reacting compound is a salt derived from guanidine.